

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

ACTELION PHARMACEUTICALS
LTD. and ACTELION CLINICAL
RESEARCH, INC.,

Plaintiffs/Counterclaim-Defendants,

V.

APOTEX INC., APOTEX CORP.,
ROXANNE LABORATORIES, INC.,
and ACTAVIS ELIZABETH LLC,

Defendants/Counterclaim-Plaintiffs.

Civil Action No. 1:12-cv-05743-NLH-AMD

Honorable Noel L. Hillman

ECF Filing

**DEFENDANTS/COUNTERPLAINTIFFS' JOINT SUR-REPLY IN OPPOSITION TO
PLAINTIFFS/COUNTERDEFENDANTS' MOTION TO STAY DISCOVERY**

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INTRODUCTION

Defendants/Counterplaintiffs Apotex Inc., Apotex Corp., Roxane Laboratories, Inc., and Actavis Elizabeth LLC respectfully submit this joint sur-reply in opposition to Plaintiffs/Counterdefendants Actelion Pharmaceuticals Ltd.'s and Actelion Clinical Research, Inc.'s (collectively, "Actelion") Motion to Stay Discovery. Actelion's reply brief repackages the same arguments made in its opening brief and does not identify any new grounds for the extraordinary and disfavored remedy of a discovery stay. By persisting in its argument that discovery should be stayed based on its filing of a potentially dispositive motion, Actelion continues to ignore that the mere filing of a disposition motion, even one that can be decided without discovery, does not by itself constitute "good cause" for a discovery stay. Because Actelion still has not made a "clear and unmistakable" showing that its potentially dispositive motion will be granted, the filing of that motion is not grounds for a discovery stay.

Further, even if Actelion's filing of a potentially dispositive motion provided some grounds for a discovery stay (which it does not), where there is a fair possibility that such a stay would damage someone else, Actelion must show a clear case of hardship in being required to go forward with discovery. Here, there is more than a fair possibility that a discovery stay would damage not only Defendants/Counterplaintiffs, but also patients who purchase the two drug products at issue in this case, as well as third-party payors such as insurance companies and federal and state governments. Moreover, Actelion still has not shown that it would suffer any hardship in being required to go forward with the phased discovery that has been proposed. Accordingly, for the reasons discussed below and in Defendants/Counterplaintiffs' opposition, Actelion's Motion to Stay Discovery should be denied.

ARGUMENT

I. ACTELION'S POTENTIALLY DISPOSITIVE MOTION IS NOT GROUNDS FOR A DISCOVERY STAY BECAUSE IT HAS NOT MADE A "CLEAR AND UNMISTAKABLE" SHOWING THAT THE MOTION WILL BE GRANTED.

Actelion continues to take the position that the mere fact that it filed a Motion for Judgment on the Pleadings and to Dismiss the Counterclaims is sufficient grounds for a discovery stay. This position ignores the law in this District. A discovery stay is an "extraordinary remedy" that is "not favored," and "the mere filing of a dispositive motion does not constitute 'good cause' for the issuance of a discovery stay." *Forrest v. Corzine*, 757 F. Supp. 2d 473, 476 (D.N.J. 2010); *Coyle v. Hornell Brewing Co.*, Civil No. 08-2797 (JBS/JS), 2009 WL 1652399, at *3 (D.N.J. June 9, 2009) (citations omitted).

The filing of a dispositive motion can provide the requisite "good cause" for a discovery stay only where it is "clear and unmistakable" that the dispositive motion will be granted. Ex. C to Opp'n, Order 2, *Ariano Castro, M.D., P.A. v. Sanofi Pasteur Inc.*, No. 2:11-cv-07178, Dkt. No. 102 (D.N.J. July 18, 2012) (rejecting the defendant's motion to stay discovery based on the filing of cross-motions to dismiss because the court was "unable to find on the record before it that there [was] a 'clear and unmistakable result' that [it] could reach on the cross-motions"); *Gerald Chamales Corp. v. Oki Data Ams., Inc.*, 247 F.R.D. 453, 454 (D.N.J. 2007) (denying the defendants' motion to stay discovery based on the filing of a summary judgment motion because the court was "unable to conclude that there [was] only one result that could be reached"). Otherwise, the issuance of a discovery stay would require predicting how the dispositive motion will be decided, which courts in this District have declined to do. *Gerald Chamales Corp.*, 247 F.R.D. at 454 ("In the absence of a clear and unmistakable result, this Court does not believe the issuance of a protective order should depend upon its prediction of how the District Judge will decide defendants' dispositive motion."). In contending that the Court need only "assess

whether the dispositive motion ‘appears to have substantial grounds or, stated another way, does not appear to be without foundation in law’” (Reply 3 (citing a case from the Middle District of Pennsylvania)), Actelion misstates the law in this District.

Actelion has failed to meet its burden to show that it is “clear and unmistakable” that its potentially dispositive motion will be granted. It is not enough that, by filing the dispositive motion, Actelion’s counsel certified to the Court that the “legal contentions [in the motion] are warranted by existing law.” (Reply 4 (citing Rule 11).) If it were, then a discovery stay would be appropriate any time a party files a dispositive motion that does not violate Rule 11.

Indeed, a review of the parties’ briefs on Actelion’s potentially dispositive motion will reveal that it is unlikely to be granted. Although Actelion makes much of the fact that Congress has not enacted legislation requiring brand-name manufacturers to sell samples to generic manufacturers (Reply 4), its argument completely misses the point: the issue in this case is *not* whether Actelion has violated some independent obligation under the Federal Food, Drug and Cosmetic Act to supply potential generic competitors with samples (or even whether such a statutory obligation exists), but whether Actelion’s failure to do so constitutes anticompetitive conduct under federal and state antitrust laws and also violates state common law. The forthcoming opposition to Actelion’s dispositive motion will demonstrate that (i) Defendants/Counterplaintiffs have pled that Actelion’s conduct does violate those laws, and (ii) there is no absolute right under the antitrust laws that somehow protects Actelion’s conduct, as it errantly suggests. Indeed, fully consistent with that position, Congress *has* stated that brand-name manufacturers shall not use safety measures required by the U.S. Food and Drug Administration (such as restrictive distribution arrangements) to “block or delay” approval of a potential generic drug, as Actelion has done in this case. 21 U.S.C. § 355-1(f)(8).

The unlikelihood of Actelion's potentially dispositive motion being granted is reinforced by the fact that, in the case most clearly on point, a district court in this Circuit *denied* such a motion filed by the brand-name manufacturer. *See* Ex. D to Opp'n, Order, *Lannett Co. v. Celgene Corp.*, No. 2:08-cv-03920, Dkt. No. 42 (E.D. Pa. May 28, 2010). At a minimum, *Lannett*, as the only case to have decided a virtually identical dispositive motion, is relevant to determining whether Actelion's dispositive motion is likely to be granted.

Actelion's attempt to argue that a discovery stay is warranted because its potentially dispositive motion can be decided without discovery (Reply 5) also misses the mark. If the Court were to accept this argument, then a discovery stay would be appropriate almost any time a party files a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) or a motion for judgment on the pleadings under Rule 12(c). However, that is not the law in this District. *See, e.g., Coyle*, 2009 WL 1652399, at *4 (denying a motion to stay discovery pending a ruling on a Rule 12(b)(6) motion to dismiss); Ex. C to Opp'n, Order, *Ariano Castro, M.D., P.A.*, No. 2:11-cv-07178, Dkt. No. 102 (D.N.J. July 18, 2012) (rejecting a motion to stay discovery pending a ruling on cross-motions to dismiss under Rule 12(b)(6)).

The cases cited by Actelion are distinguishable on their facts and, if anything, underscore why a stay is not appropriate in this case. Contrary to what Actelion suggests (Reply 6), the issuance of a discovery stay in *Mann v. Brenner*, 375 F. App'x 232, 239 (3d Cir. 2010), had nothing to do with any failure by the plaintiff to argue that he needed discovery to respond to the defendants' motion to dismiss. In fact, the plaintiff argued that he needed discovery to respond to the defendants' motion, but the court found that such discovery "would be futile" because "none of [the plaintiff's] claims entitle[d] him to relief" – essentially finding it was clear and

unmistakable that the defendants' motion to dismiss would be granted. *Id.*¹ As for the only case that Actelion cites from this District, *Patel v. Barbo*, No. 08-cv-3586, 2011 WL 1882422, at *2 n.4 (D.N.J. May 17, 2011) (Reply 5), it is easily distinguishable, and has no precedential value, for at least three reasons: (i) discovery there had been ongoing for several months and the plaintiff did not cooperate with the defendant's discovery requests, prompting the defendant to file a motion to dismiss based on the plaintiff's failure to cooperate and to request a discovery stay; (ii) the defendant made a showing that the remaining discovery sought by the plaintiff, who himself had not cooperated with discovery, would have imposed a financial burden on the defendant; and (iii) in issuing a discovery stay, the court did not provide any reason for its decision, but merely handwrote the word "Granted" on the two-page letter from the defendant requesting the stay. *See* Ex. A, Letter Order, *Patel v. Barbo*, No. 08-cv-3586, Dkt. No. 48 (D.N.J. Nov. 18, 2010).² Accordingly, Actelion's filing of a potentially dispositive motion is not grounds for a discovery stay.

¹ While a few cases cited in *Mann* from other jurisdictions suggest that a motion to dismiss may be resolved before proceeding to discovery, those cases are not binding here and are inconsistent with the well-established case law in this District. To the extent that the Court even considers those cases, it is worth noting that at least one of them reasoned that "defendants [should be able] to challenge the legal sufficiency of complaints without subjecting themselves to discovery." *Rutman Wine Co. v. E. & J. Gallo Winery*, 829 F.2d 729, 738 (9th Cir. 1987). In this case, however, Actelion is not the recipient of unwanted litigation; it *initiated* the litigation and is now seeking a discovery stay while it moves for judgment on its own complaint. Actelion should not be able to avoid a foreseeable consequence of its decision to litigate – subjecting itself to discovery – merely because it may be inconvenienced.

² The cases that Actelion cites from other jurisdictions also are distinguishable. For example, in *Weisman v. Mediq*, Civ. A. No. 95-1831, 1995 WL 273678, at *2 (E.D. Pa. May 3, 1995) (Reply 3, 5), the court found that the plaintiff would not be "prejudiced by a stay in any significant way," and that any delay from a discovery stay would be minimal because the defendants' motion to dismiss would "be decided in the near future." Unlike Defendants/Counterplaintiffs here, the plaintiff in *Weisman* did not demonstrate or even argue that a delay of the case would cause further damage to him or to others. Instead, the plaintiff argued "without evidentiary support, either direct or by inference," that a delay would "result in loss or alteration of potential evidence or witness testimony," and the court found that the

II. GIVEN THE DAMAGE THAT A DISCOVERY STAY WOULD CAUSE TO DEFENDANTS/COUNTERPLAINTIFFS AND OTHERS, ACTELION'S FAILURE TO SHOW THAT IT WOULD SUFFER ANY HARDSHIP IN PROCEEDING WITH DISCOVERY IS FATAL TO ITS MOTION.

Actelion “must make out a clear case of hardship or inequity in being required to go forward [with discovery], if there is even a *fair possibility* that the stay . . . will work damage to someone else.” *Forrest*, 757 F. Supp. 2d at 478 (emphasis added) (citation omitted); *Coyle*, 2009 WL 1652399, at *3 (emphasis added) (citation omitted). Actelion has failed to do so.

As Defendants/Counterplaintiffs have demonstrated, there is more than a “fair possibility” of damage to themselves, patients who purchase Tracleer and Zavesca, and third-party payors that would result from a discovery stay. (Opp’n 9-10.) In essence, each day that Actelion refuses to sell samples of Tracleer and Zavesca to Defendants/Counterplaintiffs is another day that consumers are delayed the benefits of cheaper prices that would result from generic competition. *Id.* Unable to refute this point, Actelion contends that Defendants/Counterplaintiffs are not harmed because they did not immediately sue Actelion after it refused to sell them samples. However, the fact that Defendants/Counterplaintiffs tried to negotiate an efficient resolution – one that is not “unprecedented” but has been (and remains) the industry standard – rather than resorting to drawn-out litigation does not negate the fact that Defendants/Counterplaintiffs would suffer additional damage from a discovery stay.

In addition, Actelion ignores altogether the damage that a discovery stay would cause to patients who purchase the two drug products at issue and third-party payors such as insurance

defendants were aware of the “importance of preserving documents and other evidence.” *Id.* at *2 & n.2. And similar to *Patel*, the plaintiff in *Fujita v. United States*, 416 F. App’x 400 (5th Cir. 2011) (Reply 2), obtained a significant amount of discovery (approximately 1,900 pages of documents) over more than a one-year period, and the court stayed discovery until the plaintiff complied with his own discovery obligation to disclose an expert witness because, without doing so, the plaintiff could not survive the defendant’s dispositive motion.

companies and federal and state governments. Accordingly, contrary to Actelion's argument (Reply 6), cases such as *Forrest* and *Gerald Chamales Corp.* where a motion to stay discovery was denied in part because others would have been prejudiced by a stay are not distinguishable.

In light of the foregoing, Actelion's failure to identify any specific prejudice that it would suffer from proceeding with discovery is fatal to its request for a discovery stay. *See Forrest*, 757 F. Supp. 2d at 478 (finding that the moving party had not satisfied its "burden" to make out a clear case of hardship or inequity); *see also Cipollone v. Liggett Grp., Inc.*, 785 F.2d 1108, 1121 (3d Cir. 1986) ("[b]road allegations of harm, unsubstantiated by specific examples or articulated reasoning" are not sufficient) (citations omitted). Defendants/Counterplaintiffs have already shown that the phased discovery proposed by them – which would be limited to written discovery and the exchange of core or "priority" documents in the first three-to-four months – would not be unduly burdensome or expensive. (Opp'n 8.) Actelion's only response is that such discovery "would be unnecessarily wasteful and burdensome *if* Actelion's dispositive motion is granted." (Reply 6 (emphasis added).) However, the same thing could be said for any case in which a motion to stay discovery pending a ruling on a dispositive motion is considered. In any event, the core documents that would be subject to the first phase of discovery (such as agreements with distributors) could be easily produced (in fact, Defendants/Counterplaintiffs have reason to believe that Actelion has already produced at least some of those documents to the Federal Trade Commission). Therefore, cases such as *Coyle* in which a motion to stay discovery was denied in part because the requested discovery could be easily produced are not distinguishable (Reply 6), but are directly on point.

Finally, Actelion's suggestion that it "has an interest in the speedy resolution" of this case (Reply 6) is not credible. As a monopolist with the exclusive right to manufacture and sell the

two drug products at issue, Actelion has an overwhelming economic interest in perpetuating the status quo for as long as possible. Its request for a discovery stay is just another tactic to further delay the development of competing generic products.

CONCLUSION

For the foregoing reasons, Actelion has failed to demonstrate that this is an extraordinary case warranting a stay of discovery. Its Motion to Stay Discovery should be denied, and discovery should commence immediately.

Date: February 19, 2013

Respectfully submitted,

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and ACTAVIS ELIZABETH LLC)	
)	
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_____)	

I, A. Richard Feldman, hereby certify that, on February 19, 2013, I caused a true and correct copy of Defendants/Counterplaintiffs' Joint Sur-Reply in Opposition to Plaintiffs/Counterdefendants' Motion to Stay Discovery to be served via the Court's ECF System upon the following:

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